

### **REMARKS**

Applicants respectfully request further examination and reconsideration in view of the above amendments and the arguments set forth fully below. In the Office Action mailed July 5, 2006, claims 1 and 3-19 have been rejected and claim 1 has been objected to. In response, the Applicants have submitted the following remarks and amended claims 1 and 18. Accordingly, claims 1 and 3-19 are still pending. Favorable reconsideration is respectfully requested in view of the amended claims and the remarks below.

#### **Drawing Objections**

The drawings have been objected to under 37 C.F.R. §1.83(a) as not showing every feature of the invention specified in the claims. In response, the Applicants have amended claims 1 and 18 to cancel the features of "...wherein the measuring of the 3-D QRST angle is effectuated with an area detection method." Accordingly, the Applicants respectfully request that the objection to the drawings is withdrawn.

#### **Specification Objections**

Within the Office Action, the specification has been objected to as failing to provide prior antecedent basis for the claimed subject matter. In response, the Applicants have amended claims 1 and 18 to remove the feature of "...wherein the measuring of the 3-D QRST angle is effectuated with an area detection method." Accordingly, the Applicants respectfully request that the objection to the specification is withdrawn.

#### **Claim Objections**

Within the Office Action, claim 1 has been objected to because the language and format of the claim is awkward. By the above amendment, the Applicants have amended claim 1 according to the Examiner's suggestion. Accordingly, the Applicants respectfully request that the objection to claim 1 be withdrawn.

Rejections Under 35 U.S.C. §112

Claims 1 and 3-19 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. By the above amendment, the Applicants have amended claims 1 and 18 to remove the feature of “....wherein the measuring of the 3-D QRST angle is effectuated with an area detection method.” Accordingly, the Applicants respectfully request that the rejection to claims 1 and 3-19 are withdrawn.

Claim Rejections Under 35 U.S.C. §101

Claim 1 has been rejected under 35 U.S.C. §101 because the claimed invention lacks patentable utility. Within the Office Action it is stated that the final limitation of claim 1 appears to be an abstract idea rather than a practical application of that idea. By the above amendment, the Applicants have amended the final limitation of claim 1 to read “calculating a variation between the first value and the second value,” thus adding a tangible, useful and concrete method step. Accordingly, the Applicants respectfully submit that the rejection under 35 U.S.C. §101 be withdrawn.

Rejections Under 35 U.S.C. §102

Claims 1 and 3 have been 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,136,690 to Anderson (hereinafter Anderson). The Applicants respectfully disagree with this rejection.

Anderson relates to vector analysis of ECG arrhythmias. Within the Office Action, it is stated that Anderson teaches employing by measuring a 3-D QRST angle measured using an area detection method or loop measuring method commonly associated with a 3-D vector cardiograph using a three lead system such as the Frank lead system or the modified McPhee lead system. The Applicants respectfully submit that the background of the Anderson invention mentions the three lead Frank lead system and McPhee lead systems, but nowhere in the Anderson reference, does the reference teach or

make obvious the use of a three lead system to determine or measure a 3-D QRST angle. In fact, the Anderson reference describes an invention that uses two ECG leads, but does not teach utilizing a three lead system, which renders the possibility of Anderson measuring a 3-D QRST angle impossible. In short, Anderson does not teach defining a relationship between depolarization and repolarization, including measuring a 3-D QRS-T angle.

In contrast to the teachings of Anderson, the present invention utilizes a 3-D QRS-T angle, which is more representative of true heart dye pole. The present invention utilizes three lead ECG systems in order to appropriately measure a 3-D QRST angle, which is something the invention taught in Anderson cannot do.

The amended independent claim 1 is directed to a method of using an electrocardiogram signal comprising assessing a patient's cardiac vulnerability to sudden cardiac death by determining a first value representative of a 3-D QRST angle relationship for a first beat of the electrocardiogram signal, determining a second value representative of the 3-D QRST angle for the second beat of the electrocardiogram signal, wherein determining the first and second values defines a relationship between depolarization and repolarization, and calculating a variation between the first value and the second value. As discussed above, Anderson does not teach or make obvious the steps of determining a first and second value representative of a 3-D QRST angle. For at least these reasons, the independent claim 1 is allowable over the teachings of Anderson.

Claim 3 is dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Anderson. Accordingly, claim 3 is also allowable as being dependent upon an allowable base claim.

*Rejections Under 35 U.S.C. §103*

Claims 6-7 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson. Claims 6-7 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over teachings of Anderson. Accordingly, claims 6-7 are also allowable as being dependent upon an allowable base claim.

Claims 4-5 and 8 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application No. 2004/0220635 to Burnes (hereinafter Burnes). The Applicants respectfully disagree with this rejection. Claims 4-5 and 8 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Anderson. Accordingly, claims 4-5 and 8 are also allowable as being dependent upon an allowable base claim.

Claims 9 and 18 are rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view U.S. Patent No. 4,732,157 to Kaplan et al. (hereinafter Kaplan). The Applicants respectfully disagree with this rejection.

Kaplan merely relates to an apparatus and method for quantifying variability and physiological wave forms, but like Anderson, does not teach or make obvious defining a relationship between depolarization and repolarization, including measuring a 3-D QRS-T angle. Therefore, for the same reasons as discussed above with respect to claim 1, the Applicants respectfully submit that claim 18 is also allowable over the teachings of Anderson, Kaplan and their combination. Claim 9 is dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Anderson. Accordingly, claim 9 is also allowable as being dependent upon an allowable base claim.

Claims 10 and 11 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of U.S. Patent No. 5,265,617 to Verrier et al. (hereinafter Verrier). Claims 10-11 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Anderson. Accordingly, claims 10-11 are also allowable as being dependent upon an allowable base claim.

Claims 12 and 14-16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Ralph et al. (hereinafter Ralph). claims 12 and 14-16 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Anderson. Accordingly, claims 12 and 14-16 are also allowable as being dependent upon an allowable base claim.

Application No. 10/824,950  
Amendment Dated October 5, 2006  
Reply to Office Action of July 5, 2006

Claim 13 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Ralph and Verrier. Claim 13 is dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Anderson. Accordingly, claim 13 is also allowable as being dependent upon an allowable base claim.

Claim 17 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Ralph and Burnes. Claim 17 is dependent upon the independent claim 1. As discussed above, independent claim 1 is allowable over the teachings of Anderson. Accordingly, claim 17 is also allowable as being dependent upon allowable base claim.

Claim 19 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Kaplan and Verrier. Claim 19 is dependent upon independent claim 18. As discussed above, the independent claim 18 is allowable over the teachings of Anderson and Kaplan. Accordingly, Claim 19 is also allowable as being dependent upon an allowable base claim.

For these reason, Applicants respectfully submit that all claims are now in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at (414) 271-7590 to discuss the same that any outstanding issues may be expeditiously resolved.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP

By: Christopher M. Scherer  
Christopher M. Scherer  
Reg. No. 50,655

Andrus, Sceales, Starke & Sawall, LLP  
100 East Wisconsin Avenue, St. 1100  
Milwaukee, WI 53202  
(414) 271-7590